October 9, 2019

Merit Medical Systems, Inc.
Shamsa Karimi
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K191596
Trade/Device Name: Arcadia™ Balloon Catheter
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG, NDN
Dated: September 11, 2019
Received: September 12, 2019

Dear Ms. Karimi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191596

Device Name
Arcadia ™ Balloon Catheter

Indications for Use *(Describe)*

The Arcadia ™ Steerable and Straight Balloon Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. These balloon catheters are to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement for use during percutaneous vertebral augmentation, such as kyphoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(408) 770-1115
	Contact Person:	Shamsa Karimi
	Registration Number:	1721504
Subject Device	Trade Name:	Arcadia™ Balloon Catheter
	Common/Usual Name:	Inflatable Balloon Tamp
	Classification Name:	Arthroscope, Orthopedic Manual Surgical Instrument, Polymethylmethacrylate (PMMA) bone cement
	Regulatory Class:	II
	Product Code:	HRX, HXG, NDN
	21 CFR §:	888.1100, and 888.4540, 888.3027
	Review Panel:	Orthopedics
Predicate Device	**Predicate #1:**	
	Trade Name:	Kyphon® Express II™ Inflatable Bone Tamp
	Classification Name:	Arthroscope, Orthopedic Manual Surgical Instrument, Polymethylmethacrylate (PMMA) Bone Cement
	Premarket Notification:	K123771
	Manufacturer:	Medtronic Sofamor Danek USA
	Predicate#2:	
	Trade Name:	Osseoflex® SB
	Classification Name:	Arthroscope, Polymethylmethacrylate (PMMA) Bone Cement
	Premarket Notification:	K141930
	Manufacturer:	Osseon LLC
	This predicate device has not been subject to a design-related recall.	
Device Description	The Arcadia Balloon Catheters consist of a Y-Adapter with a dual-lumen catheter shaft and a balloon. The inner shaft lumen contains a stylet (either straight or articulating). The outer lumen is an inflation conduit for the balloon. A valved luer port on the Y-adapter allows for connecting an inflation device to inflate and deflate the balloon. Two	

	marker bands are printed on the shaft and serve as indicators of when the distal tip of the balloon catheter has reached the distal end of the working cannula of the StabiliT® Introducer. Radiopaque markers are located on the proximal and distal end of the balloon to aid in balloon placement prior to inflation. The exterior surface of balloon is covered by a lubricant which ease access through the introducer cannula. The Arcadia Steerable Balloon Catheter features a mechanism that enables steering of the device. The Arcadia Straight Balloon Catheter has a removable stylet.
Indications for Use	The Arcadia™ Steerable and Straight Balloon Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. These balloon catheters are to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement for use during percutaneous vertebral augmentation, such as kyphoplasty.

Comparison to Predicate Devices

The design and technological characteristics of the subject Arcadia Balloon Catheter are substantially equivalent to the predicate devices, Kyphon® Express II™ Inflatable Bone Tamp and Osseoflex® SB.

The comparison between the subject and the predicate devices were based on the following:

- Intended Use
- Indications for Use
- Labeling
- Basic Design and Material
- Principle of Operation/Fundamental Technology
- Performance
- Sterilization
- Biocompatibility

Summary of Technological Characteristics of the Subject Device to the Predicate Devices

Attribute		**Predicate Device Osseoflex® SB (Steerable)**	**Predicate Device Kyphon® Express II™ Inflatable Bone Tamp (Straight)**	**Subject Device Arcadia Balloon Catheter (Steerable and Straight)**
Balloon Inflation Medium		60% Contrast	60% Contrast	60% Contrast
Device Materials	Balloon	Polyurethane	Polyurethane	Polyurethane
	Catheter	Polyurethane	Polyurethane	Polyurethane
	Marker Bands	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium
Balloon Length (pre-(inflation)/Maximum Balloon Volume		10mm/(2mL), 20mm/(4mL)	10mm/(3mL), 15mm/(4mL), 20mm/(5mL)	10mm/(3mL), 15mm/(4mL), 20mm/(5mL), 25mm/(7mL), 30mm/(8mL)
Max Inflation Pressure		400 psi	700 psi	700 psi

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence	
Performance Test Summary	
Test Performed	**Acceptance Criteria**
Biocompatibility Testing	Device meets applicable ISO 10993-1:2018 requirements
Insertion and Withdrawal Force	Insertion and withdrawal of the device through the introducer do not create forces that would damage the balloon catheter.
Inflated Balloon Dimensions (Unconstrained)	Inflated balloon dimensions are similar to similarly labeled predicate devices.
Articulated Angle and Radius	Articulation profile of steerable devices matches that of tools used to create channels in the bone for balloon placement.
Deflation Time with Contrast Solution	Deflation time is similar to predicate devices of the same size and volume profile.
Constrained Max Pressure Testing	Device is capable of sustaining its maximum rated pressure when the balloon is constrained.
Unconstrained Burst Volume	Device exceeds its maximum volume rating before burst failure
Tensile Force Testing	Device material and bond strengths exceed forces that may be applied during normal clinical use.
Summary of Clinical Tests for Determination of Substantial Equivalence	
N/A- No clinical test was conducted for this submission.	
Substantial Equivalence Conclusion	
Based on the indications for use, intended use, design, safety and performance testing, the subject Arcadia Balloon Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate Devices, Kyphon® Express II™ Inflatable Bone Tamp [K123771] and Osseoflex® SB [K141930].	

Performance Data

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject device, Arcadia Balloon Catheter was conducted based on the risk assessment and based on the requirements of the following international standards:

- FDA Guidance Document: Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009: Biological evaluation of medical devices— Tests for in vitro cytotoxicity.
- ISO 10993-10:2010: Biological evaluation of medical devices— Tests for irritation and skin sensitization
- ISO 10993-11:2017: Biological evaluation of medical devices— Tests for systemic toxicity.
- USP 41- NF 36: 2018, <151>, Pyrogen Test (USP Rabbit Test)
- ASTM D 4169-16: Standard practice for performance testing of shipping and systems.
- ASTM F88M/F88M-15: Standard test method for seal strength of flexible barrier materials.
- ASTM F1140/F1140M-13: Standard test method for internal pressurization failure resistance of unrestrained packages.
- ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F1980-16: Standard Guide for accelerated aging of sterile barrier systems for medical devices.
- ASTM F2096-11: Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test).
- EN ISO 2233:2000: Packaging—Complete filled transport packages and unit loads—Conditioning for testing.
- ISO 11607-1:2006: Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)].
- ISO 11607-2: 2006: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]
- ISO 11137-2:2013: Sterilization of health care products – Radiation - Part 2 Establishing the sterilization dose.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation and testing for the subject Arcadia Balloon Catheter was conducted in accordance with ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and FDA Guidance Document*:* Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2016)". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

The Arcadia Balloon Catheter is categorized as an externally communicating device with tissue/bone/dentin contact for a limited (< 24 hours) duration. All biocompatibility testing met the requirements of the respective test methods, thus supporting the biocompatibility of the subject device, Arcadia Balloon Catheter.

Performance Data cont.

Performance Testing

Design verification and validation testing were completed to establish the performance of the subject device, Arcadia Balloon Catheter and substantial equivalence to the predicate device.

Design Verification Testing:

- Pre-Inflation Dimensional Analysis
- Insertion and Withdrawal Force
- Inflated Balloon Dimensions (Unconstrained)
- Articulated Angle and Radius
- Deflation Time with Contrast Solution
- Constrained Max Pressure Testing
- Unconstrained Burst Volume
- Tensile Force Testing

Design validation testing confirmed that the subject device, Arcadia Balloon Catheter conforms to user needs and intended uses.

	Performance testing demonstrates equivalence between the subject device and the predicate device. A risk management assessment was performed and found that the subject device does not introduce any new risk related to its safety or effectiveness.
Summary of Substantial Equivalence	Based on the indications for use, intended use, design, safety and performance testing, the subject Arcadia Balloon Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate Devices, Kyphon® Express II™ Inflatable Bone Tamp [K123771] and Osseoflex® SB [K141930].

Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject device, Arcadia Balloon Catheter was conducted based on the risk assessment and based on the requirements of the following international standards: • FDA Guidance Document: Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. • ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009: Biological evaluation of medical devices— Tests for in vitro cytotoxicity. • ISO 10993-10:2010: Biological evaluation of medical devices— Tests for irritation and skin sensitization • ISO 10993-11:2017: Biological evaluation of medical devices— Tests for systemic toxicity. • USP 41- NF 36: 2018, <151>, Pyrogen Test (USP Rabbit Test) • ASTM D 4169-16: Standard practice for performance testing of shipping and systems. • ASTM F88M/F88M-15: Standard test method for seal strength of flexible barrier materials. • ASTM F1140/F1140M-13: Standard test method for internal pressurization failure resistance of unrestrained packages. • ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye penetration. • ASTM F1980-16: Standard Guide for accelerated aging of sterile barrier systems for medical devices. • ASTM F2096-11: Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test). • EN ISO 2233:2000: Packaging—Complete filled transport packages and unit loads—Conditioning for testing. • ISO 11607-1:2006: Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]. • ISO 11607-2: 2006: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)] • ISO 11137-2:2013: Sterilization of health care products – Radiation - Part 2 Establishing the sterilization dose.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation and testing for the subject Arcadia Balloon Catheter was conducted in accordance with ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and FDA Guidance Document*:* Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2016)". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

The Arcadia Balloon Catheter is categorized as an externally communicating device with tissue/bone/dentin contact for a limited (< 24 hours) duration. All biocompatibility testing met the requirements of the respective test methods, thus supporting the biocompatibility of the subject device, Arcadia Balloon Catheter.

Performance Data cont.

Performance Testing

Design verification and validation testing were completed to establish the performance of the subject device, Arcadia Balloon Catheter and substantial equivalence to the predicate device.

Design Verification Testing:

- Pre-Inflation Dimensional Analysis
- Insertion and Withdrawal Force
- Inflated Balloon Dimensions (Unconstrained)
- Articulated Angle and Radius
- Deflation Time with Contrast Solution
- Constrained Max Pressure Testing
- Unconstrained Burst Volume
- Tensile Force Testing

Design validation testing confirmed that the subject device, Arcadia Balloon Catheter conforms to user needs and intended uses.

	Performance testing demonstrates equivalence between the subject device and the predicate device. A risk management assessment was performed and found that the subject device does not introduce any new risk related to its safety or effectiveness. The Arcadia Balloon Catheter is qualified and labeled as a sterile, single-use device with the 6-month shelf-life at this time.
Summary of Substantial Equivalence	Based on the indications for use, intended use, design, safety and performance testing, the subject Arcadia Balloon Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate Device, Kyphon® Express II™ Inflatable Bone Tamp [K123771].